

§ 20.80

21 CFR Ch. I (4–1–03 Edition)

court action, which have not been disclosed to any member of the public, including any person who is the subject of the investigation.

(c) Any record which is disclosed to any person, including any person who is the subject of a Food and Drug Administration investigation, and any data or information received from any person who is the subject of a Food and Drug Administration investigation relating to such investigation, is available for public disclosure at that time in accordance with the rule established in § 20.21, except that:

(1) Disclosure of such records shall be subject to the other exemptions established in this subpart and to the limitations on exemptions established in subpart E of this part.

(2) The record of a section 305 hearing shall be available for public disclosure only in accordance with the provisions of § 7.87 of this chapter.

(d) Records for law enforcement purposes shall be subject to the following rules:

(1) No such record is available for public disclosure prior to the consideration of regulatory enforcement action based upon that record's being closed, except as provided in § 20.82. The Commissioner will exercise his discretion to disclose records relating to possible criminal prosecution pursuant to § 20.82 prior to consideration of criminal prosecution being closed only very rarely and only under circumstances that demonstrate a compelling public interest.

(2) After the consideration of regulatory enforcement action is closed, such records shall be made available for public disclosure except to the extent that other exemptions from disclosure in this subpart are applicable. No statements of witnesses obtained through promises of confidentiality are available for public disclosure.

(3) The consideration of regulatory enforcement action based upon a particular record shall be deemed to be closed within the meaning of this section:

(i) If it relates to administrative action, when a final decision has been made not to take such action or such action has been taken and the matter has been concluded.

(ii) If it relates to court action, when a final decision has been made not to recommend such action to a United States attorney based upon that record, or a recommendation has been finally refused by a United States attorney, or court action has been instituted and the matter and all related appeals have been concluded, or the statute of limitations runs.

(iii) If it relates to both administrative and court action, when the events described in both paragraph (d)(3) (i) and (ii) of this section have occurred.

(4) Prior to disclosure of any record specifically reflecting consideration of possible criminal prosecution of any individual, all names and other information that would identify an individual who was considered for criminal prosecution but who was not prosecuted shall be deleted unless the Commissioner concludes that there is a compelling public interest in the disclosure of such names.

(e) Names and other information that would identify a Food and Drug Administration employee shall be deleted from records prior to public disclosure only pursuant to § 20.32.

[42 FR 15616, Mar. 22, 1977, as amended at 59 FR 536, Jan. 5, 1994]

Subpart E—Limitations on Exemptions

§ 20.80 Applicability of limitations on exemptions.

(a) The limitations on exemptions established in this subpart shall apply to all Food and Drug Administration records, except as specifically provided herein. Accordingly, a record that is ordinarily exempt from public disclosure in accordance with the provisions in subpart D of this part is available for such disclosure to the extent that it falls within a limitation on the exemption contained in this subpart. For example, an investigatory record that is ordinarily exempt from disclosure under § 20.64 is disclosable to Congress in accordance with the provisions of § 20.87.

(b) Disclosure of a record to any member of the public pursuant to the provisions in § 20.81, data and information previously disclosed to the public, in § 20.82, discretionary disclosure by

the Commissioner, and in § 20.83, disclosure pursuant to a court order, shall involve the rule established in § 20.21 that the record shall be made available for disclosure to all members of the public who request it. Disclosure of a record only to the limited categories of persons and under the conditions specified in § 20.84, special government employees, in § 20.85, other Federal government departments and agencies, in § 20.86, in camera disclosure in administrative or court proceedings, in § 20.87(b), Congress, in § 20.88, State and local government officials, in § 20.89, foreign government officials, and in § 20.90, contractors, which does not result in disclosure of the record to any member of the public in an authorized manner, shall not invoke the rule established in § 20.21.

(c) Disclosure to government employees and special government employees of records exempt from public disclosure shall subject those persons to the same restrictions with respect to the disclosure of such records as any Food and Drug Administration employee.

(d) In the case of a record in a Privacy Act Record System, as defined in § 21.3(c) of this chapter:

(1) The availability to an individual, as defined in § 21.3(a), of a record about himself that is retrieved by the individual's name or other personal identifier and is contained in a Privacy Act Record System shall be subject to the special requirements of part 21 of this chapter (the privacy regulations) and shall not be subject to the exemptions in subpart D of this part except that where the system is exempt and the requested record is not available under § 21.61 of this chapter, the provisions of this part shall apply.

(2) The availability of a record about an individual to persons other than the individual who is the subject of the record shall be subject to the special requirements of part 21, subpart G, of this chapter (restrictions on disclosure in the privacy regulations), and shall not be subject to the limitations on exemptions in this subpart except as provided in part 21, subpart G, of this chapter.

§ 20.81 Data and information previously disclosed to the public.

(a) Any Food and Drug Administration record that is otherwise exempt from public disclosure pursuant to subpart D of this part is available for public disclosure to the extent that it contains data or information that have previously been disclosed in a lawful manner to any member of the public, other than an employee or consultant or pursuant to other commercial arrangements with appropriate safeguards for secrecy.

(1) For purposes of this section, an individual shall be deemed to be a consultant only if disclosure of the information was necessary in order to perform that specific consulting service and the purpose of the disclosure was solely to obtain that service. The number of consultants who have received such information shall have been limited to the number reasonably needed to perform that particular consulting service.

(2) For purposes of this section, other commercial arrangements shall include licenses, contracts, and similar legal relationships between business associates.

(3) For purposes of this section, data and information disclosed to clinical investigators or members of institutional review committees, whether required by regulations of the Food and Drug Administration, or made voluntarily, if accompanied by appropriate safeguards to assure secrecy and otherwise in accordance with this section, are not deemed to have been previously disclosed to any member of the public within the meaning of paragraph (a) of this section.

(b) Any data or information furnished to the Food and Drug Administration for a presubmission review pursuant to the procedure established in § 20.44 shall be accompanied by a statement that the information has not previously been published or disclosed to anyone other than as provided in paragraph (a) of this section.

(c) Any statement relating to prior public disclosure is subject to the False Reports to the Government Act, 18 U.S.C. 1001.

[42 FR 15616, Mar. 22, 1977, as amended at 54 FR 9038, Mar. 3, 1989; 59 FR 536, Jan. 5, 1994]